



REC'D 28 NOV 2003  
WIPO PCT

# Kongeriget Danmark

Patent application No.: PA 2002 01694

Date of filing: 04 November 2002

Applicant:  
(Name and address)  
Bang & Olufsen Medicom a/s  
Gimsinglundvej 20  
DK-7600 Struer  
Denmark

Title: Device for dispensing a medicament

IPC: A 61 M 15/00

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.



**PRIORITY DOCUMENT**  
SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH  
RULE 17.1(a) OR (b)

Patent- og Varemærkestyrelsen  
Økonomi- og Erhvervsministeriet

21 November 2003

The handwritten signature of Bo Zillo Tidemann.

Bo Zillo Tidemann

**BEST AVAILABLE COPY**



PVS

1

The present invention relates to a device for dispensing a medicament from a pressurised canister comprising a mouthpiece, a seat for engagement with the top of the canister and a housing provided with means for guiding and/or holding the canister.

5 These types of devices are used as portable inhalation devices which permit the user to inhale a medicated vapour spray where the spray may include powders, liquids or gases.

10 These types of devices are usually used by people suffering from asthma and other respiratory diseases or disabilities having difficulty breathing from time to time. Depending on the activity level of the person in question, the breathing difficulties may be more or less severe. Also inflammations or other infections or secondary diseases in the respiratory system can further aggravate the difficult breathing situation.

15 A number of medications are available to alleviate these symptoms and substantially restore the individual's ability to breathe to a normal stable situation.

20 Although there are a number of different ways in which to take medications for alleviating the problems mentioned above, one of the more common types is to have the medication mixed with an aerosol propellant in a canister. The canister is then placed in an inhalation device where after the individual suffering from breathing problems can insert a mouthpiece into the mouth and by depressing the canister in the device dispense a dose of the medication directly into the airways.

25 The canister is usually placed upside down in the device such that the dispensing nozzle and the rim of the canister is pointing downwards of the inhalation device. The nozzle rests on a seat and is guided such that upon depression of the canister by the user's hand into the device, the nozzle will be depressed and due to the overpressure created by the aerosol in the canister, a dose will be sprayed into the user's mouth. The user will then inhale the medication with the aerosol directly into the lungs.

It is a requirement that canisters of this type are fitted with a valve system whereby depression of the canister and thereby dispensing of medication through the nozzle is provided such that only one single dose per compression will be dispensed.

5      Conventional dispensers are usually two-piece structures consisting of a housing which contains the mouthpiece which is also adapted to receive the aerosol canister wherein the medication is contained. The medication is contained in the canister under pressure due to the presence of an aerosol. The canister is inserted into the housing so that the dispensing nozzle of the canister is pointed downward and oriented toward:  
10     the mouthpiece provided on the housing. The opposite end of the canister usually projects upwardly and outside the housing. The user can place the housing between the thumb and forefinger and use the thumb and forefinger or the thumb and fingers to force the canister downward and in this way release a dose of the medication into the mouthpiece and thereby inhale it into the airways and lungs.

15     For individuals suffering from mild forms of asthma or other breathing disabilities, depressing the canister into the device and thereby dispensing a dose does usually not cause a problem. However, a large number of the users of these types of devices are also suffering from other debilitations such as rheumatism or arthritis. Furthermore,  
20     small children needing asthma medications may also find it difficult to grip the prior art devices as mentioned above in that their hand are physically too small in order to be able to grip around the device and exert the necessary force in order to dispense a dose. A number of devices are therefore proposed which should aid especially users with reduced physical ability to depress the canister in order to dispense a dose. One  
25     such a device is presented in US 6,397,837 wherein the traditional inhalation device can be equipped with a lever arm device mounted on the traditional inhalation device.

One problem associated with the device mentioned above is that the lever arrangement either must be installed before every dispensing of a dose. This can cause serious  
30     problems for the user in that usually when a dose is needed, the user's ability to breathe is hampered and the stress level for the user is therefore increased. In order to assemble the device such that a dose can be dispensed, more parts have to be relocated

and assembled on the device. Another problem is that for a host of users it is desirable to carry the device around with them such that a dose can be dispensed whenever needed i.e. in the office; on the bus etc. For this purpose the users often carry their dispensing device in a pocket or in a small handbag. With the lever arm arrangement according to the prior art mentioned above there is a tendency to the lever arm becoming stuck in that it projects outside the general geometry of the device itself. This in turns means that either the device will be broken off and therefore not function or the lever arm arrangement will be disassembled causing extra trouble for the user when a dose needs to be dispensed.

10

For a number of users suffering from diseases where the medication is dispensed in the manner described above they will have different canisters containing different concentrations of the medication or even different types of medication for different diseases. The canisters and/or devices are often colour-coded in order to provide information about the medications contained in the canister. It is however a problem for the user always to have the correct canister mounted in the device as well as some of the devices are made in such a way that it is impossible to recognise the colour-coding on the canister as usually a large part of the canister is placed inside the dispensing device. It is therefore foreseeable that a situation can arise where a person suffering from any of the debilitations mentioned above will find him/herself in a situation with the wrong medication and further might inadvertently dispense a dose of a wrong medicament due to the inability of recognising the canister in the device.

25

Recently the legislative bodies in the different countries have made moves to ban the CFC-gasses which are traditionally used as aerosols in canisters of this type. CFC-gasses are being replaced by a new family of gasses known as HFA-gasses. These gasses when used as aerosols/propellants require that the gaskets and the valve arrangement in the canister are made in a different manner. For the user the result is that a higher force is needed in order to compress the canister into the inhalation device whereby the nozzle is sufficiently compressed for it to dispense a dose of the medication. As a number of the users as explained above can have limited force in their hands it becomes increasingly difficult for these persons to dispense doses when needed.

A further consideration both for producers and for the users of this type of device is the hygienic circumstance in which the device as a whole but especially the mouthpiece is manufactured, handled, stored and kept by the user. In order to protect the mouthpiece, it is customary to provide a loose cap which snugly fits onto the mouthpiece. This cap however, has a tendency to become lost, damaged or otherwise not fulfil its function. In order to alleviate this it has been suggested in the art to fasten the cap to the device itself, for example by means of a strap or to arrange a hinge such that the cap member can be pivoted away in a close position. In all the prior art devices where attachment means have been provided for keeping the cap in close proximity to the device as such, the cap can obstruct the usability of the device and hamper the dispensation of a medication dose.

It is therefore an object of the present invention to provide a device for dispensing a medicament as described above which provides for easy and safe dispensation of a dose and which furthermore alleviates the drawbacks of prior art devices as mentioned above.

The invention addresses this by providing a device for dispensing a medicament which is special in that a lever arm having means for engagement with the bottom end of the canister is pivotally fastened to the housing in one end and the free end of the lever arm when engaging the canister projects outside the housing or is flush with the housing.

By providing a lever arm, the amount of force needed by the user to depress the canister is lessened. This is especially important with the new type of propellants/aerosols in that the seals and gaskets in the canister around the nozzle makes it more difficult i.e. requires higher forces in order to compress the canister enough for a dose of medication to be dispensed.

Contrary to prior art devices, in a preferred embodiment the lever arm is only projecting outside the housing when the means for engagement of the bottom end of the canister is engaging the canister.

In an alternative embodiment the lever arm is flush with the housing. The lever arm still provides the advantages as explained above, but additionally provides for a simpler construction. In use this embodiment provides the user with more possibilities for holding and activating the device. At the same time when the lever arm is a free moving part, but integral/flush with the outer surface of the device, easy and unhindered storage of the device is assured. Furthermore, foreign matter cannot enter the device and accidentally hinder activation of the drug dispensing or an optional dose dispensing device. In one actual embodiment of the device the lever arm is the activation button. The button is arranged such that an air gap between the button and the housing lets in the air required for being able to inhale the dispensed dose through the mouthpiece.

Furthermore, as there are no projecting members of the device, it becomes easier to store in a pocket, handbag or the like and furthermore the risk of damaging the device is minimal due to the protective housing surrounding the device as such.

In a further advantageous embodiment a cap is provided for covering the mouthpiece. Said cap is pivotally mounted to the housing such that it can pivot between a closed position where the mouthpiece is completely covered and an open position in which the mouth piece is accessible.

The pivotally mounted cap makes sure that the cap is always available for covering up the mouthpiece when the mouth piece is not to be used. Although this does not constitute a 100 % hygienic protection for the mouth piece, it does provide protection against dust, sand and other foreign objects which might otherwise become stuck either inside the mouthpiece or on the surface of said mouth piece. By being able to pivot the cap away from covering the mouth piece and into an open position where the mouthpiece is not hindering the access to the mouth piece, both the hygienic protection of the mouthpiece as well as the safe keeping of the cap is assured.

In a further advantageous embodiment a shaft projecting out of the housing engages at least one aperture provided in the cap or a depression on the inside of the cap. This arrangement can, however, also be arranged such that the depression or aperture is arranged in the housing and the engaging shaft is provided on the cap. On the inside of 5 the cap adjacent the aperture or depression a cam is provided. The hinge-like arrangement of the cap constitutes a simple and a cost effective way of arranging the cap on the housing.

In a further advantageous embodiment the means for engagement with the bottom of 10 the canister comprise a yoke which yoke has a canister engagement section optionally having a shape corresponding to the bottom of the canister and an end section which, when the cap is in its close position, engages the cam provided on the cap such that the engagement section of the yoke is not in contact with the canister.

15 This mechanism makes certain that the engagement means not accidentally can be activated and the canister depressed. By depressing the canister, the nozzle will be activated and a dose will be dispensed. It is therefore not desirable to have an uncontrolled dispensing of medication. This is assured by having a mechanism which, when the cap is closed, hinders the movement of the engagement means by making the yoke 20 not moveable in a non-engaging position.

In a still further advantageous embodiment means are arranged in the cap for engagement with the housing and limiting the cap's movement with respect to the housing in the cap's open position. Hereby it is assured that the cap, when it is open, can come 25 into a firm position against the housing and thereby constitute a reaction surface. When a person wants to dispense a dose of medication, the device is usually gripped as described above in the hand of the user. This means that one part of the user's hand usually the thumb will be placed underneath the device and in this embodiment a surface of the cap will constitute the gripping section, whereas a forefinger will grip and 30 depress the lever arm. It is therefore important that the cap in its open position gives the user a firm grip upon activation. It is therefore in a still further advantageous embodiment of the invention so that the underside of the cap in its open position consi-

tutes a grip and that the grip optionally is ergonomically shaped. The economic shape can be attained by giving the surface in question a saddle-shape. With "saddle-shape" should be understood a surface which curves in two directions so that it will snugly fit into a finger joint, for example in the thumb. Furthermore, the surface of the cap can have a character which gives it non-slip properties, for example by roughening the surface by providing dimples or even by adding a high friction layer to the surface.

In a further advantageous embodiment of the invention, the lever arm is guided by three tracks provided on the inside of the housing where the guidance comprises pins arranged on the lever arm perpendicular to the lever's longitudinal direction and that said pins engage the tracks and preferable identical sets of tracks arranged symmetrically on either side of the lever: a first set of tracks in front of the canister which is generally horizontal; a second set of tracks provided in the yoke also being generally horizontal and a third set of tracks arranged behind the canister and comprising a generally straight upper section and a curved lower section.

In order to be able to describe the canister in detail and how the different parts and sections of the device are arranged in relation to each other, the relative terms "inside", "outside", "up", "down", "in front of" and "behind" shall be interpreted as imagining the device in the use situation i.e. in a situation where a user is standing vertically and inserts the device having the canister in a substantially vertical position with the nozzle section and adjacent rim of the canister placed upside down in the device. In front of the canister, means that it is close to the user's face i.e. on the same side as the mouthpiece, and behind the canister is to be understood as being away from the user's face. Inside the housing is to be interpreted as being within the volume comprised within the housing. Horizontal is consequently defined in relation to the above described use position.

In a further advantageous embodiment of the invention, the length of the lever arm is such that when the cap is in its close position and the free end of the lever arm is flush with or contained within the housing and when the cap is in its open position, the free end of the lever arm will project from the housing.

This interaction between the cap and the lever arm does in combination with the above-mentioned embodiments of the invention that the device as such has a very user friendly and storage friendly appearance. When the device is closed, there are no projecting members which can become stuck, break or otherwise give rise to unfortunate incidents. In order to activate the device, the user has to do a positive turning of the cap in order to release the engagement means from the cam via activation of the yoke, make the lever arm project from the housing and thereafter grip the device such that part of the users hand will rest on the grip provided by the cap in its open position and thereafter depress the lever arm for dispensing a dose.

In a still further advantageous embodiment of the invention, the lower most section of the yoke and the abutting section of the cam are correspondingly shaped such that a resilient member urging the yoke against the cam will provide a certain resistance against pivotal movement of the cap in its close position. By providing the device with these features, the user will have to make a positive turning of the cap member in order to overcome the resistance forces arising due to the abutting contact between the cam and the yoke. This is further assured by the provision of a resilient member, for example in the shape of a spring which will maintain the yoke in an abutting relationship with the cam in the cap's close position.

The abutting section of the cam can be shaped with a convex or concave section with a corresponding concave or convex section in the end of the yoke such that a positive close position will be felt by the user as these abutting sections engage.

Also during storage and transport of the device, the positive engagement between two abutting sections will minimize the risk of the device accidentally opening.

An additional problem associated with this type of device is the fact that a canister can contain 100 or more doses of medication. The user will therefore have a tendency to forget how many doses have been dispensed or how many doses are left in the device. This can give rise to severe problems especially if the user is travelling and therefore

does not have access to the regular supply of medicaments should the canister run empty.

- Furthermore, in certain situations it is desirable to have an indication about when a new canister/device should be bought. For some types of medication it is becoming a legal requirement that an indicating device shall be provided for this type of devices. It is therefore in a still further advantageous embodiment of the invention foreseen that a user is able to see how much is left in the canister by means of a dose dispensing mechanism arranged inside the housing such that a member engaging the rim of the canister will be depressed together with the depression of the lever arm and that said member will transmit the depression to a dose dispenser for registration of a delivered dose and that the dose dispensing mechanism comprises means visible on the housing for indicating the number of dispensed doses or the number of remaining doses.
- Either indication i.e. whether it is the number of dispensed doses or the number of remaining doses is interesting information for the user. When indicating the number of dispensed doses it is necessary to know the total number of doses contained in the canister whereas when the dose dispensing mechanism indicates the number of remaining doses, it is necessary to set the dose dispenser when the canister is inserted on the correct number of doses contained in the canister. Alternatively, if it is not desirable to indicate an exact number, the dose dispenser can be arranged to indicate when there is a low dose content in the canister, for example by the lettering "low" or by indicating with a colour code on the readout that only a limited number of doses is available from the canister.
- In some embodiments of the invention the dose indicating mechanism is arranged as an integral part of the canister holding means. In this way it is impossible to disengage the indicating means from the canister, whereby errors arising due to inadvertently replacing one canister with another and in this manner perhaps get a wrong content indication can be avoided.

10

A dose dispensing device is disclosed, which benefits from the input from the lever arm as described above in that the lever arm causes another large movement/displacement. This displacement makes it easy to detect that an intentional dose has been dispensed or is in the process of being dispensed in that the signal from the lever arm is clear and easily detectable. The input to the dose dispenser consists of mainly two things; firstly a force or movement urging the dose dispensing mechanism to move and secondly activation of the dispensing mechanism.

In the art there is suggested a number of dose dispensing mechanism, where saw teeth on an indicating wheel are pushed forward by a moveable mechanism, for example in the shape of a secondary lever arm. The secondary lever arm is often activated by the canister's movement and the entire travel length of the secondary lever arm corresponds to the travel length of the canister during the dispensation of a medication dose. There are, however, in the beginning of the movement as well as in the end of the displacement of the secondary lever arm a certain tolerance, which due to the very small displacements of the secondary lever arm in relation to the saw tooth can give rise to inaccuracies in the indication of the number of dispensed doses or, alternatively, the number of remaining doses in the canister. Consequently, there is a need for a dose dispenser, which is more reliable and which operates with tolerances of a magnitude where they are negligible such that reliable information is indicated in the indicating wheels.

In order to indicate the remaining content or used content in the canister indicating devices comprising one or more wheels can be installed. The indicating devices are often installed such that the user easily can determine the content directly by reading the dial (indicating wheels) arranged behind a transparent section of the housing.

The indicating device may comprise one or more wheels arranged on a common or on separate axles. On the one or more wheels are provided means for engagement with an input arrangement translating the input from the user that a dose is being dispensed into an input that one or more of the indicating wheels shall be moved correspondingly to indicate that one more dose is being dispensed.

In one preferred embodiment two indicator wheels are provided on a common axis. In front of the two indicator wheels, a front cover is provided. In the front cover is provided a window area through which markings on the two wheels can be viewed. On the front is in one example indicated the numbers 1 to 12 and next to each number arranged circumferentially along the periphery of the wheel is arranged a window through which a small segment of the second wheel can be seen. On the second back wheel is circumferentially arranged the numbers 0 to 9 twice. When the front cover and the two wheels are arranged such that the two wheels are arranged around the common axis, it will be possible through the window area on the front cover to see one of the number 0-12 including a window on the front wheel and through that window in the front wheel see one of the number 0-9 on the back wheel. As each dose is dispensed, the back wheel will move onto the next higher number. The front wheel will be activated to move by means of for example a gear wheel interposed between the two indicator wheels such that the front wheel will be activated to move one notch when the back wheel moves from 9 to 0.

Through the window in the front cover, one or two digits on the front wheel will be visible as well as through the window in the front wheel the numbers on the back wheel will be visible. In this manner it is possible to provide an exact counter of the number of dispensed doses indicating either the number of remaining doses or the number of dispensed doses.

It is obvious that the back wheel also can be numbered from 0-9 and therefore only contain ten digits or thirty digits or more. The choice depends on how the input is transmitted in order to activate the dispensing device.

The two wheels can also have different diameters such that the front wheel has a smaller diameter than the back wheel whereby it will be possible, without a window in the front wheel, to view the numbers on the back wheel.

## 12

- In an alternative embodiment according to the invention a dose dispenser, which dose dispenser comprises indicating means for indicating the available content in the canister, which means comprises two indicating wheels turnably arranged on respective perpendicular axis; a secondary lever arm having means for engaging at least one of the indicating wheels and an activating protrusion; a pivotable activating member comprising a first curve or a circular section translating into a second curve or linear section translating into a third curve or a circular section arranged such that the secondary lever arm will abut and slide on said sections during a count.
- 10 In this manner a count, i.e. registration and indication of a dispensed dose, comprises three distinct movements by the secondary lever arm engaging the indicating wheels. The first movement is caused by the protrusion sliding along a first curve/circular section. By this movement the protrusion on the lever arm engaging the indicating wheel is brought into engagement with engagement means arranged on the indicating wheel.
- 15 Hereby any slack and tolerances in the system is taken out and the dispense mechanism is prepared for the count. The count is activated by the protrusion sliding along the second, preferably linear, surface on the lever arm. As the lever arm has engaged and taken up any slack in the system between the indicating wheel and the lever arm, the lever arm will be depressed and thereby the indicating wheel will be turned/rotated
- 20 due to the sliding movement along the second surface. As the second surface translates into the third curved, circular shaped surface the lever arm will not move any further thus allowing the camister to be fully activated. In this manner a definite input is created by depressing the lever arm in order to activate the mechanism such that one dose is being registered in the indicating wheels.
- 25 In a further advantageous embodiment of the invention a part activated by the lever arm comprises engagement means for engaging the indicating wheels. The indicating wheels can be supplied with a groove which is arranged in a circular surface of at least one of the wheels at a distance from the rim. The groove comprises spaced radial sections connected with curved or linear sections. In a further embodiment said groove may for example comprise interconnecting and alternating radial and peripheral sections arranged such that a part of the lever arm is inserted and slidably arranged in said

groove and further that means for urging at least one wheel to rotate is provided. The groove may also be shaped as a saw tooth track, wherein radial sections are interconnected with linear or curved sections (corresponding to the peripheral sections) alternating at either end of the radial section. Also, other patterns or designs of the  
5 groove can be contemplated within the principle of the rotation of the wheel being hampered by engagement means on a secondary lever arm engaging notches or the like (radial sections) on the wheel.

The groove will be a guidance track for the secondary lever arm's movement. If the  
10 secondary lever arm encounters a radial section, the wheel will not be able to rotate further. By moving the secondary lever arm in a radial direction, i.e. depressing the canister and dispensing a dose, the dispensing wheel will be released from its engagement with the secondary lever arm and be able to rotate. The length of the rotation is determined by the length of the peripheral groove section. This length should correspond to the indication of one dispensed dose. By furthermore providing means for  
15 urging the wheels to rotate, for example in the shape of a pre-stressed spring or similar device, the side of the groove will always be in contact with the part of the secondary lever arm engaging the groove. By the next radial movement of the secondary lever arm the wheel will again be released and be able to rotate the equivalent of a peripheral section's length.  
20

This embodiment is especially advantageous in that the dispensing mechanism does only require the absorption of small and negligible tolerances in that the formation of the groove will dictate the movement of the indicating wheel.

25 In a further advantageous embodiment the peripheral sections of the groove have different and increasing lengths along the periphery of the wheel. Hereby it becomes possible to have an unlinear indication on the indicating wheel. This is especially advantageous in that when the device is new and unused the user is certain that a large number of doses is available. The interesting question to a user is, especially when a large  
30 number of doses have been dispensed, how many doses are left in the canister. It can therefore be advantageous to have an exact and clear indication of the number of doses

remaining in the canister when there is only a low number of doses left. This can be provided by having very short peripheral sections on the indicating wheel in the area with a large number of doses left in the canister and relatively longer sections when there are only a few doses left in the canister. Hereby is facilitated that the movement of the wheel is larger and thereby the indication clearer.

5 In a further advantageous embodiment the interconnected and alternating radial and peripheral sections are arranged in a spiral on the surface of the at least one wheel. In this configuration it is possible to have an unlinear indication with a large number of 10 doses, whereby the indicating wheel will do more than one revolution in order to indicate the number of doses dispensed.

The invention furthermore comprises a method for counting dispensed doses from a device as described above, wherein by depressing the lever arm which thereby rotates 15 around the fastening point of the lever arm in the housing, the protrusion comprising a first curve or circular section translating into a second curve or linear section translating into a third curve or linear sections slides on a secondary lever arm such that the secondary lever arm has an end part which engages means on at least one of two indicating wheels arranged on a mutually perpendicular rotating axis such that the downward movement of the secondary lever arm creates a rotation on at least one indicator 20 wheel.

In a further preferred embodiment of the invention, at least part of the device for example the housing, the cap and/or the lever arm is coloured or otherwise marked according to a predefined code representing a specific drug contained in the canister. 25 This embodiment is especially useful for patients which suffer from different diseases at the same time which require different medication. Also patients requiring different concentrations of their medicament at different times, for example a higher concentration before going to sleep, would also easier be able to determine the correct device to 30 use in any given situation.

By having a specific colour for the medication suitable for treatment for one disease or in a given time, the user will be able to recognise and use the correct device according to the symptoms.

5 In some of the embodiments of the present invention, the canister is completely enclosed within the device whereby it is impossible for the user to read information which may be printed on the outside of the canister. This information can also be provided on the device, but as an additional safety caution, a distinctive colour coding should also be provided. This is due to the fact that in acute cases, the user having more than one device should not have any doubt as to which one to use according to the situation and as there furthermore is usually a high level of stress in these situations paired with perhaps reading impairment requiring glasses it does provide an additional safety aspect to distinctively colour code the device itself.

15 Turning to the more specific construction of the device, the device in a further preferred embodiment of the invention is constructed such that the means for engaging the bottom of the canister are integral with the lever arm. When the lever arm and the means for engaging the bottom of the canister is one and the same member, for example constituting an outside surface of the housing, fewer parts are needed in the assembly of the device. This has some advantages in the fact that the fewer parts comprised in the device, the fewer parts can be misassembled or malfunction during the device's expected lifetime. Furthermore, by integrating the means for engaging the bottom of the canister in the lever arm, the effect of the lever arm is maintained and the device is presented as an integral unit without any members extending substantially outside the housing of the device, especially when the cap is in its closed position.

20  
25  
30 In a further advantageous embodiment, the cam provided on the cap in the caps closed position engages the top of the canister, whereby downward movement of the canister is prevented and thereby prevents the dispensing of a dose. By positively locking the canister in this position wherein it is impossible for it to be activated in order to dispense a medicine dose through the nozzle, it is assured that the device as such will not

dispense a dose inadvertently. It requires a positive action from the user side, namely the pivoting of the cap member in order to firstly gain access to the mouthpiece through which inhalation of the medication is done and at the same time releasing the canister from a locked position such that upon activation of the means for engaging the bottom of the canister, the top of the canister including the nozzle means can be brought into a position where a medication dose can be dispensed.

The lever arm's function is mainly to reduce the force necessary to dispense a dose as explained above. This is particularly true for the canisters comprising HFA-propellants/aerosols where gaskets of a different type are needed in order to make the canister leak proof. These gaskets require a higher force in order to depress the canister for dispensing a dose. The lever arm is therefore in a further preferred embodiment constructed such that the lever arm has a length corresponding to increasing the actual force delivered to the bottom of the canister by the engagement means by a ratio in the range of from 2:1 to 5:1, most preferred around 3:1.

A further advantage in increasing the force transferred to the canister is that it is assured that a positive dispensation and complete depression of the canister can be obtained since it will be easier for the user to depress the lever arm completely. Also by providing a lever arm, the need to use force by the user diminishes in that the lever arm multiplies the force. Furthermore, a better coordination between the activating movement e.g. the depression of the lever arm and the inhaling of the dispensed dose is achieved.

In a further preferred embodiment, the lever arm is a pivotal section of the housing constituting at least part of the top surface of the device and the lever arm is pivotally fastened to the housing in one end of the lever arm. Also in a still further embodiment, the lever arm adjacent its free end comprises a downwardly projecting hook section and a corresponding grip section is arranged on the inside of the housing such that the hook and the grip section can be brought into abutting contact and thereby create a snap-joint.

- As the lever arm in this embodiment of the invention also is a part of the housing, it is important for the integrity of the housing that the lever arm is kept in a position where it is flush with the rest of the housing. The hook and grip sections when engaged by the snap-action creating the snap-joint provide for the downward depression movement of the lever when the means for engaging the bottom of the canister is activated such that an unproblematic ejection of a dose can be performed. When the canister moves back up and thereby pushes the engagement section up. The upward movement of the canister is limited by its ability to reset and the lever arm being a section of the housing has a limited movement due to the fact that the hook section abuts the grip section. By adjusting these two, it is possible to ensure that the lever arm does not engage the bottom of the canister and at the same time that the surface of the lever arm is kept at a level where the top surface of the lever arm is substantially flush with the rest of the housing.
- For some applications it will be desirable to produce the canister, the dose indicating activating means and the dose indicating means as one integral unit which cannot be disassembled without destroying one of the components. The unit can advantageously comprise a part of the surface section of the housing. By this arrangement, the medication corresponding to the colour code of the section of the housing has not been replaced, altered or in any other way tampered with such that the user can be assured that the medication in the canister corresponds with the colour code and, furthermore, that the amount or number of indicated doses in the dose indicating device corresponds to the amount or number of doses in the canister.
- The invention will now be explained in more detail with reference to the accompanying drawing. It should be noted however that the invention is not limited to the specific embodiments as described above, but is only limited by the scope of the appended claims.
- In the drawing

## 18

Fig. 1-3 illustrates a schematic first embodiment of the device in a closed, open and activated position.

In Fig. 4, 5 and 6 a second embodiment of the invention is illustrated.

Fig. 7 illustrates a schematic construction of the dose indicator wheel arrangement.

5 Fig. 8 illustrates a schematic dispensing device.

Fig. 9 illustrates a schematic lever arm arrangement.

Fig. 10 illustrates an alternative groove configuration.

Fig. 11 illustrates an alternative groove configuration.

Fig. 12 to 16 illustrate different embodiments of the dose indication means.

10

The same elements will be given the same reference numbers in all drawings.

The present invention is explained with reference to a canister containing the medication and a propellant. The canister comprises a bottom, cylindrical sides and a top. The 15 top comprises a rim where the cylindrical sides are assembled or merge with the top. In the top is arranged a nozzle for dispensing the medication.

Inside the canister in immediate connection with the nozzle is arranged a valve wherein the actual measuring of each dose to be dispensed takes place.

20

As schematically illustrated in Fig. 4, the canister 6 comprises a bottom 60 and cylindrical sides 61. Where the top 62 is joined with the sides 61, a rim 63 is formed. The nozzle is indicated by 7.

25

Fig. 1 is a principle sketch of how the device in one embodiment of the invention can be mechanically constructed. The device 1 comprises a housing 2, a cap 3 pivotally connected to the housing by a hinge-like construction 4. Covered by the cap 3 is a mouthpiece 5 through which the medication contained in the canister 6 having nozzle means 7 can be dispensed.

30

In the figures the canister 6 is shown in an upside down position which is to be understood that the nozzle means 7 of the canister are pointing downwards.

A lever arm 8 is provided for reducing the force needed to press the canister 6 against the seat 59 such that a medication dose will be dispensed.

- 5 The lever action is guided by three tracks 9, 10, 11 arranged in the housing. In order to guide the lever 8 in the tracks 9, 10, 11 pins 12 are provided perpendicular to the lever for guidance in the tracks 9, 10, 11. In the closed position as illustrated in Fig. 1 the cap 3 completely hides the mouthpiece 5. In this position no part of the lever arm projects outside the housing 2. For illustration purposes, the lever arm 8 in Fig. 1 has been indicated as projecting outside the housing, but in the actual device the track 9 will be comprised inside the housing and partly covered by the cap 3. Likewise the free end i.e. the end of the lever arm not connected with pins to a track is also completely flush with the device. As can be seen from Fig. 1, the two tracks 9 and 10 are substantially horizontal. The third track 11 comprises a linear section 13 and a curved section 14.
- 10 15 The track 10 is provided on a yoke-mechanism 15 connected to the lever arm. The yoke-mechanism 15 comprises means 16 for engaging the bottom of the canister 6.

- Inside the cap 3 a cam 17 is provided in connection with the hinge-like 4 connection between the cap and the housing. The cam 17 and the bottom of the yoke 18 are in abutting relationship when the cap is closed such that the means 16 for engaging the bottom of the canister cannot exert any pressure on the bottom of the canister and thereby inadvertently dispense a dose into the cap.

- 25 When opening the cap as illustrated in Fig. 2 access is gained to the mouthpiece 5. At the same time the yoke 15 is released from its abutting relationship with the cam 17 and due to the very low pressure caused by the spring member 18, the means 16 for engaging the bottom of the canister 6 are moved into a position where the means 16 very lightly touches the canister 6.

- 30 At the same time the lever arm 8 is moved downwards because of the yoke's 15 downward movement due to the pressure from the spring 18 such that part of the lever arm 8 will project from the housing 2. This movement is guided by the three tracks 9,

10, 11 wherein the pins 12 can slide in respect of the movement caused by the lever arm.

In Fig. 3 the cap is in its completely open position whereby means 19 having engaged 5 the housing 2 and in this way blocked further movement by the cap 3 in relation to the housing 2. The lever arm 8 can now easily be depressed whereby a dose 20 can be ejected through the mouthpiece and into the respiratory system of a user. When the lever arm is released after the dose has been dispensed, the resiliency built into the nozzle section of the canister will force the canister upwards into a position as illustrated in Fig. 2. For this embodiment of the invention to work, it is very important that 10 the resilient member 18 is weaker than the means built into the canister for resetting into the closed position as illustrated in Fig. 2. The spring member 18 only serves to depress the yoke and thereby the engagement means 16 into abutting contact with the canister 6 whereby the lever arm is moved from a stored position flush with the housing to an exposed position where a part of the lever arm projects from the housing as 15 illustrated in Fig. 2. The movement of the lever arm from the position as indicated in Fig. 2 to the position indicated in Fig. 3 where a dose is disposed is done manually by the user by gripping the device, for example with the thumb on an abutment surface 21 on the cap and a forefinger on the projecting section of the lever arm 8 and forcing the lever arm downwards.

In Fig. 4-6 is illustrated how a canister is inserted into an embodiment of the invention. In Fig. 4 the device 1 is in its canister-receiving position. In this position the integrated means 16 for engagement of the bottom of the canister and the lever arm 8 are 25 opened by pivoting the lever arm around the pivotal connection 22. Hereby access is created to the interior of the device 1. The cap 3 is closed and the mouthpiece 5 is thereby covered.

In Fig. 5 the canister 6 is inserted into the housing 2 until it comes into abutting contact with the cam 17 on the cap 3. It is thereby impossible to insert the canister further 30 into the housing. Thereafter the lever arm 8 is pivoted as indicated by the arrow 23. The lever arm in its free end, i.e. the end which is not fastened to the pivotal connec-

tion 22, is supplied with a hook section 24. A corresponding grip section 25 is provided on the housing 2 such that when the lever arm is pivoted into a closed position as illustrated in Fig. 6 the hook section 24 will abut the grip section 25 such that the lever arm 8 by depression can move downwards but upwards movement is hindered by the hook and grip sections 24, 25. A spring-member 18 can be provided which spring-member 18 abuts the lever arm 8 such that the hook section 24 when not depressed is kept in contact with the grip section 25.

In order for the user to dispense a dose from the canister 6, it is necessary to pivot the cap 3 into its open position as illustrated in Fig. 3 whereby the cam 17 comes out of its abutting relationship with the top of the canister 6. By depressing the lever arm 8, the nozzle of the canister 6 will dispense a dose.

In the two embodiments illustrated above access for the user to the canister is hindered either because of the closed nature of the housing 2 as illustrated in Fig. 1-3 or by the hook and grip sections illustrated in Fig. 4, 5 and 6. The snap-joint created by the hook section 24 and the grip section 25 effectively avoids unintended access to the interior of the housing and thereby to the canister by a user. On the other hand, the snap-joint provides for the possibility of manufacturing the device in a place different from the mounting of the canister into the device such that devices can be produced in one place, canisters in a second place and the whole assembly of the device and canister can take place in a third location. The snap-joint furthermore prevents a user from removing a canister from the device. Hereby is avoided that the colour-coding or other means of indicating what kind of medication is contained within the housing does not correspond to the canister actually comprised in said housing.

In fig. 7 two indicator wheels 30,31 are indicated arranged on mutually perpendicular rotating axis 32,33. The first indicator wheel 30 has means for engagement 34 arranged such that the indicator engagement means provided for example by a second lever arm can rotate the indicator wheel 30 one step at a time. The indicator wheel 30 can be equipped with numbers or other means for indicating the number of doses left in the canister. This indication would be arranged on the rim 35 of the wheel. As the

## 22

indicating wheel 30 is rotated around the axis 32, the means 36 will per revolution push the second indicating wheel 31 one step. This is caused by the engagement means 37.

- 5      The indicator wheel 31 will have its dose indicating numbers or colours on a front surface 38 of the wheel 31. As the wheel 30 rotates, the numbers from 0 to 9 could for example be indicated on the rim 35. As the engagement means 36 engages the engagement means 37 provided on the second indicator wheel 31, this will cause movement of one notch on the indicator wheel 31. By providing the second indicator wheel 10      31 with the number 1 to the number of doses in a canister divided by 10, it becomes possible to indicate exactly the number of doses dispensed or alternatively the number of doses left in the canister. This is due to the fact that the engagement means 36 will push the engagement means 37 one notch and thereby add or subtract a factor 10 from the indicating means provided on the surface 38 of the indicator wheel 31.
- 15      Turning now to fig. 8, alternative means for registering and indicating the dispensation of a dose is indicated. The canister 6 is hereby schematically arranged in contact with a lever arm 39. The lever arm has an end part 40 which engages a groove provided in a surface 42 of an indicating wheel 43.
- 20      By depressing the canister 6 translation of the downward movement by the means here schematically indicated as a box 44 will translate this movement into a movement of the end of the secondary lever arm 40 such that the end of the lever arm will move gradually towards the centre 45 of the indicating wheel 43. Due to the means 46 provided for urging the indicating wheel 43 to rotate in the direction indicated by the arrow A, the peripheral section 47 of the groove 41 will move past the end of the lever arm 40 until the radial section 48 of the groove engages the end of the lever arm 40 and thereby stops further rotation. By arranging suitable indication means on the indicating wheel 43 the rotation of the indicating wheel 43 can correspond to indicating 25      one dose dispensed.
- 30

By varying the length  $a$  of the peripheral sections, it will be possible to have an unlinear representation of the number of doses dispensed.

In Fig. 10 and 11 alternative configurations of the groove are illustrated. The main principle of the groove is the provision of radial sections or notches interconnected with groove sections allowing the end of the secondary lever arm to be stopped by the radial sections and the wheel to rotate through the interconnecting groove sections.

In fig. 9 an alternative embodiment for activating the dose indicating means is illustrated. A mechanism for activating the secondary lever arm engaging the indicating wheel is illustrated. The lever arm 8 being the same lever arm as described above with respect to the embodiments illustrated in figs. 1-6 is equipped with a protrusion consisting of three distinct sections. A first section 50 being in the shape of a curve or circular translating into a second section 51 preferably curved shaped or linear translating into a third section 52 being curved or circular in shape. These sections engage a protrusion 53 provided on a secondary lever arm 54 such that depression of the secondary lever arm will occur in three distinct movements. Firstly by engaging the first section 50 any slack between the end of the lever arm 55 and means arranged on an indicating wheel 34 will be absorbed. As the protrusion 53 slides on the second surface 51, the actual depression and thereby movement of the indicating wheel 30 will occur. As the lever arm 8 is further depressed, the protrusion 53 will slide on the surface 52 whereby the pressure created by the end of the lever on 55 on the means for engagement 34 will lessen and the rotational movement of the indicator wheel 30 will subside. Hereafter the dose is completely dispensed and the user will release the lever arm 8, whereby it will be pushed back into its original position by the spring member 18 and at the same time release the end of the lever arm's 55 engagement with the means 34 such that the lever arm 54 can move back into the position indicated in fig. 9.

The box indicated in fig. 8 by reference number 44 can be constructed in a similar fashion as illustrated schematically in fig. 9.

In figs. 12-16, an alternative embodiment of the indicating means is illustrated. Fig. 12 illustrates a front cover 70 comprising a window area 71. Fig. 13 illustrates a front wheel 72 on which the numbers 0-12 have been arranged on a peripheral section along the periphery of the wheel. Next to each number is a window 73 provided.

5

In fig. 14 a back wheel 74 is illustrated. Along the periphery of the wheel, the numbers 0-9 are provided twice. By superposing the two wheels and the front cover, it will be possible to view the numbers through the window 71 in the front cover such that the numbers on the front wheel 72 as well as the numbers provided on the back wheel 74 will be visible through the window 73 such that the actual number, i.e. the combination of the number on the front wheel 72 and the number on the back wheel 74 will be visible through the window 71.

10

15

In fig. 15 the window 71 is illustrated, wherein the numbers on the front wheel 72 are visible along with the window 73 provided in the front wheel such that the numbers 75 on the back wheel 74 are visible through the window 71 in the front cover and the window 73 in the first disk becomes visible. In the illustrated example "120" doses are remaining in the canister.

20

Naturally, the disks can be arranged to count upwards or downwards, depending on choice. Likewise, the numbers can be given any suitable colour or different colours.

In fig. 16 is illustrated a special embodiment where the front wheel 72 has a smaller radius than the back wheel 74.

25

A method of assembling the device may comprise the following steps:

- the cap means are brought into its closed position, and if an access lid is provided in the top of the housing for allowing access through an opening to the interior of the housing this lid is removed from said opening;
- the pivotal engagement means are pivoted away from the housing, thereby allowing access to canister receiving means arranged inside the housing, where

30

25

the canister receiving means comprises a seat means for receiving the top end of a canister, and means for guiding the canister inside the housing;

- a canister is inserted into the housing with its top down i.e. its ejecting nozzle first, such that the top nozzle of the canister engages the seat;
- 5 - optionally a spring member is arranged on a spring seat or the engagement section, said spring members free end projecting upwards;
- the engagement means and optionally the lever arm is pivoted into abutting contact with the bottom of the canister, optionally compressing the spring member, and thereby either engages a snap joint or where a lid is provided,
- 10 the lid optionally compressing the spring member is replaced on the housing.

**CLAIMS**

1. A device for dispensing a medicament from a pressurised canister, comprising a mouthpiece, a seat for engagement with the top of the canister and a housing provided with means for guiding and/or holding the canister, characterised in that a lever arm comprising means for engagement with the bottom end of the canister is pivotally fastened to the housing in one end and the free end of the lever arm when engaging the canister projects outside the housing or is flush with the housing.  
5
2. A device according to claim 1, characterised in that a lever arm comprises means for engagement with the bottom end of the canister is pivotally fastened to the housing, and that a cap is pivotally arranged such that the cap can be pivoted into a closed position where it covers the mouthpiece and an open position where the mouthpiece is accessible, and that said cap comprises means for abutting a lower end of the canister or the means for engagement with the bottom end of the canister when the cap is in its closed position such that the canister cannot be activated accidentally.  
10
3. A device according to claim 1, characterised in that a cap is provided for covering the mouthpiece, said cap is pivotally mounted to the housing, such that it can pivot between a closed position where the mouthpiece is completely covered, and an open position in which the mouthpiece is accessible.  
15
4. A device according to claim 2 or 3, characterised in that a shaft projecting out of the housing engages at least one aperture or recess provided in the cap or at least one aperture or recess is provided in the housing wherein a shaft projecting out of the cap can engage, and that on the inside of the cap, adjacent the aperture or recess, a cam is provided.  
25
5. Device according to claim 1 or 2, characterised in that the means for engagement with the bottom of the canister comprises a yoke which yoke has a canister engagement section optionally having a shape corresponding to the bottom of the canister, and an end section, which when the cap is in its closed position engages the cam  
30

provided on the cap, such that the engagement section of the yoke is not in contact with the canister.

5       6. Device according to claim 2, 3, 4 or 5, characterised in that means are arranged in the cap for abutting on the housing and limiting the caps travel with respect to the housing in the caps open position.

10      7. Device according to claim 6, characterised in that the underside of the cap in its open position constitutes a grip and that the grip optionally is ergonomically shaped.

15      8. Device according to claim 1 or 4, characterised in that the lever is guided by three tracks provided on the inside of the housing where the guidance comprises pins arranged on the lever perpendicular to the levers longitudinal direction, and that said pins engages the tracks and preferably identical sets of tracks arranged symmetrically on either side of the lever; a first set of tracks in front of the canister which is generally horizontal; a second set of tracks provided in the yoke also being generally horizontal and a third set of tracks arranged behind the canister and comprising a generally straight upper section and a curved lower section.

20      9. Device according to claim 1 or 4, characterised in that the length of the lever is such that when the cap is closed the free end of the lever is flush with or contained within the housing, and when the cap is opened the free end of the lever will project from the housing.

25      10. Device according to any preceding claim, characterised in that a dose dispensing mechanism is arranged inside the housing, such that a member engaging the rim of the canister will be depressed together with depression of the lever, and that said member will transmit the depression to a dose indicator for registration of a delivered dose, and that the dose indicating mechanism comprises means visible on the housing for indicating the number of dispensed doses or number of remaining doses.

11. Device according to any preceding claims, characterised in that at least a part of the housing is coloured according to a predefined code representing a specific drug contained in the canister.
- 5 12. Device according to any of the claims 1 to 11, characterised in that the means for engaging the bottom of the canister are integral with the lever arm.
- 10 13. Device according to any of the proceeding claims, characterised in that the lever arm has a length corresponding to increasing the actual force delivered to the bottom of the canister by the engagement means by a ratio in the range of from 2:1 to 5:1 and most preferred 3:1.
- 15 14. Device according to any of the claims 1 to 13, characterised in that the lever arm is a pivotal section of the housing constituting at least part of a top surface of the device and that the lever arm is pivotably fastened to the housing in one end of the lever arm.
- 20 15. Device according to claim 14, characterised in that the lever arm adjacent its free end comprises a downwardly projecting hook section, and that a corresponding grip section is arranged on the inside of the housing such that the hook and the grip sections can be brought into abutting contact and thereby create a snap joint.
- 25 16. Device according to any of the preceding claims, characterised in that a dose dispenser is provided, and that said dose dispenser comprises:
  - indicating means for indicating the available content in a canister, which means comprises one or more indicating wheels;
  - a secondary lever arm having means for engaging at least one of the indicating wheels;
  - and an activating protrusion;
  - a pivotable activating member comprising a first curve or circular section translating into a second curve or linear section translating into a third curve or
- 30

circular section, arranged such that the lever arm will abut and slide on said sections during a count.

17. Device according to claim 16, characterised in that

- 5        - a groove is arranged in a circular surface of at least one of the wheels at a distance from the rim, said groove comprising spaced radial sections connected with curved or linear sections arranged such that a part of the lever arm is inserted and slidably arranged in said groove;
- means for urging at least one wheel to rotate.

10

18. Device according to any of claims 16 or 17, characterised in that the non-radial sections of the groove has different and increasing length along the periphery of the wheel.

15

19. Device according to any of claims 16, 17 or 18, characterised in that the groove is arranged in a spiral on the surface of the at least one wheel.

**ABSTRACT**

The present invention relates to a device for dispensing a medicament from a pressurised canister comprising a mouthpiece, a seat for engagement with the top of the canister and a housing provided with means for guiding and/or holding the canister.

5 The invention provides a device for dispensing a medicament which is special in that a lever arm having means for engagement with the bottom end of the canister is pivotally fastened to the housing in one end and the free end of the lever arm when engaging the canister projects outside the housing or is flush with the housing.

10 (fig. 1)

Modtaget

04 NOV. 2002

PVS

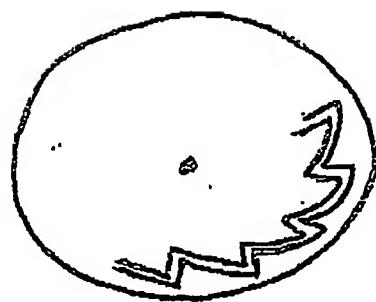
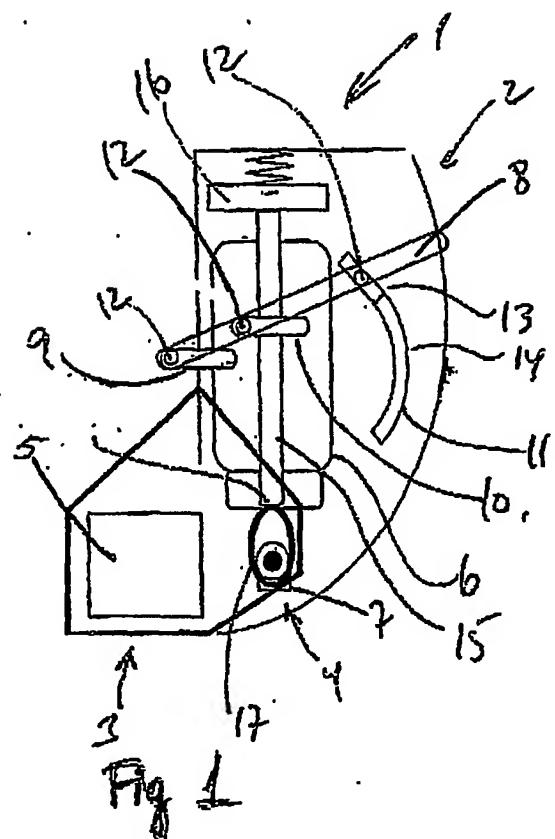


Fig 10

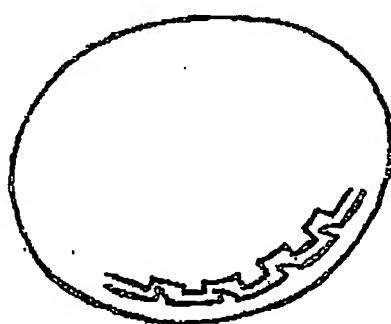
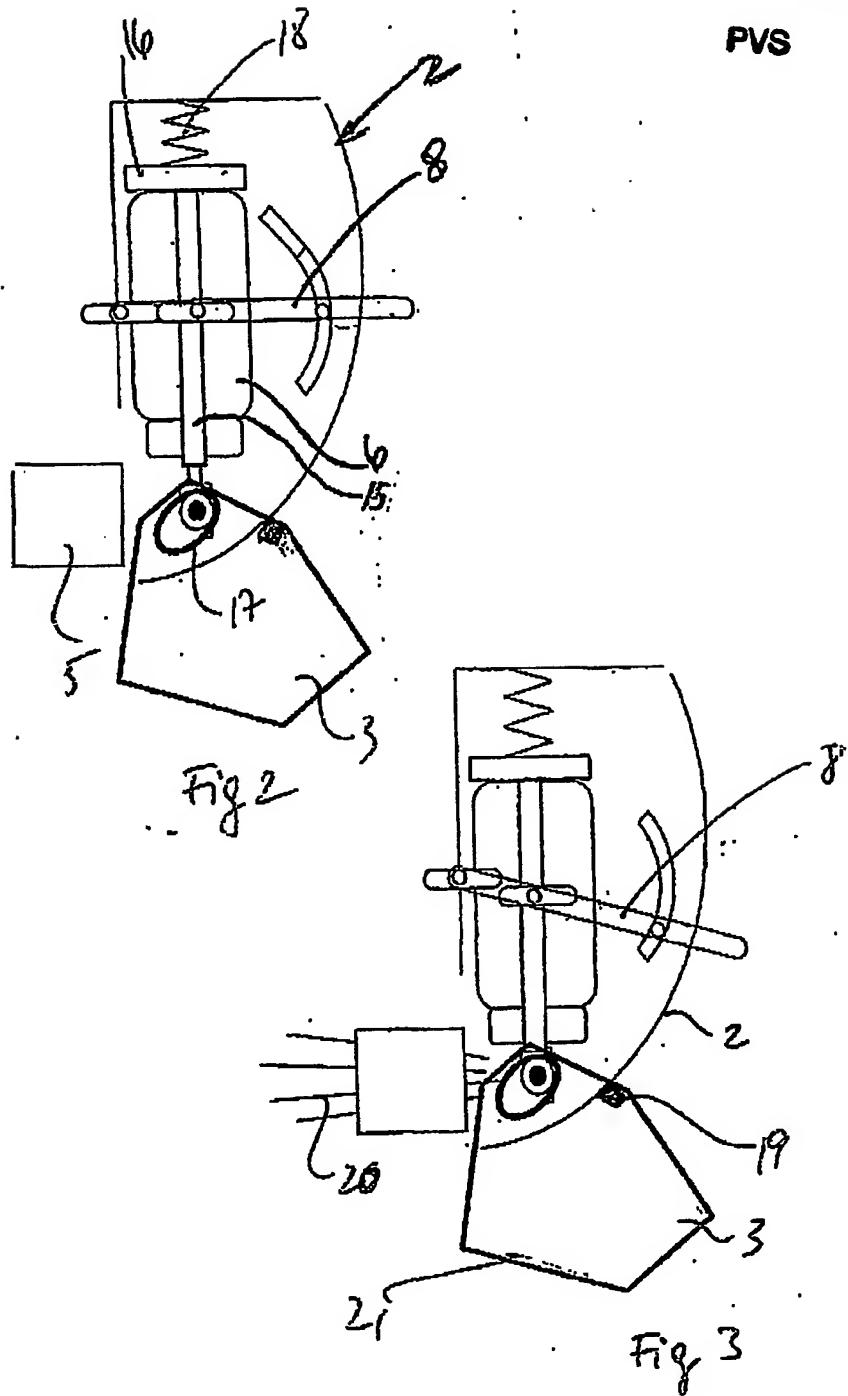


Fig 11

Modtaget

04 NOV. 2002

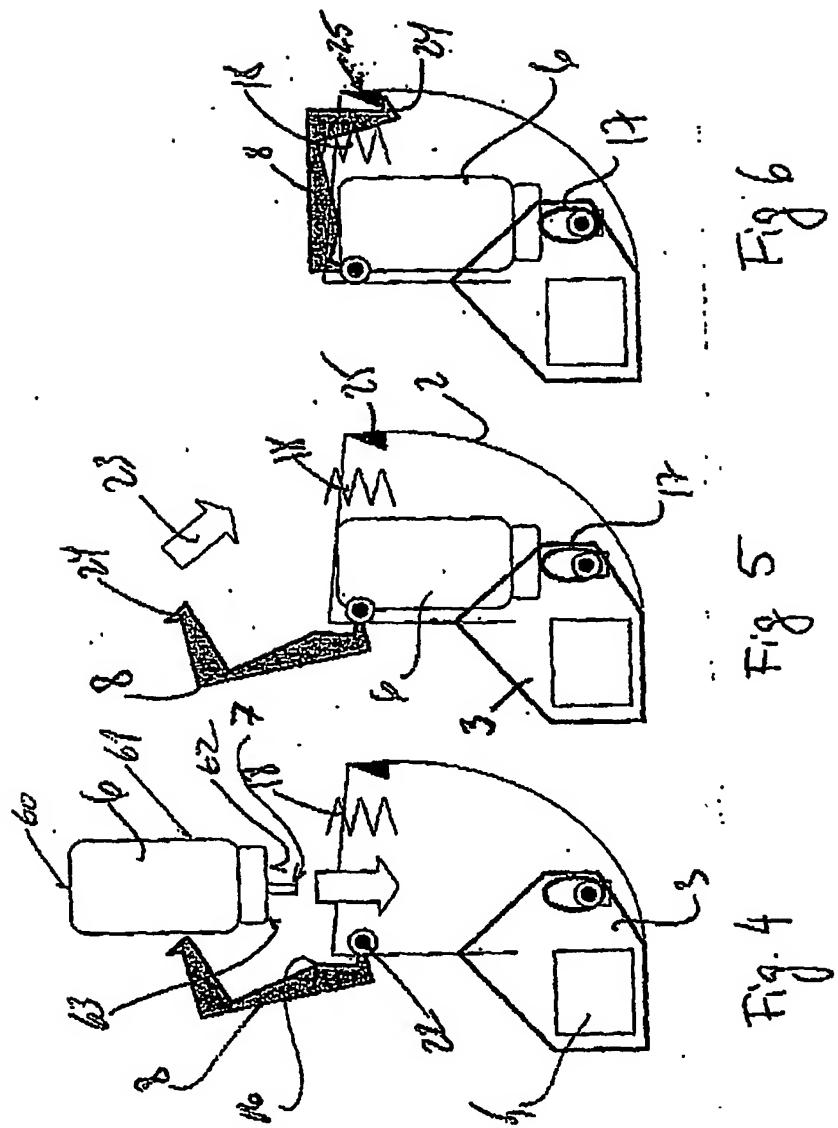
PVS

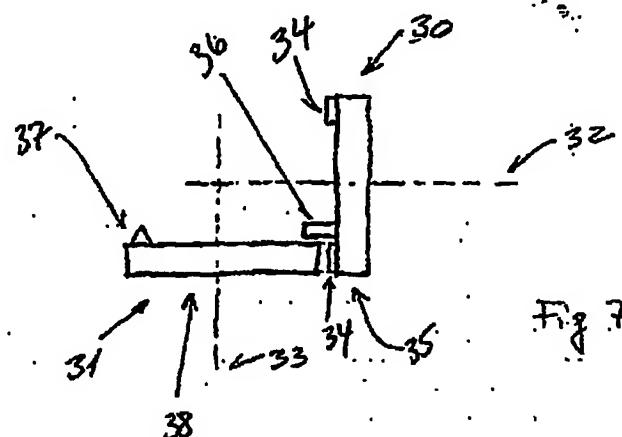


Modtaget

04 NOV. 2002

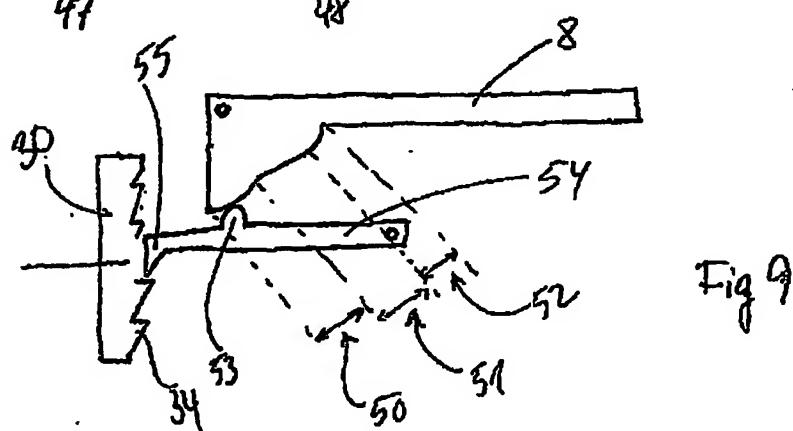
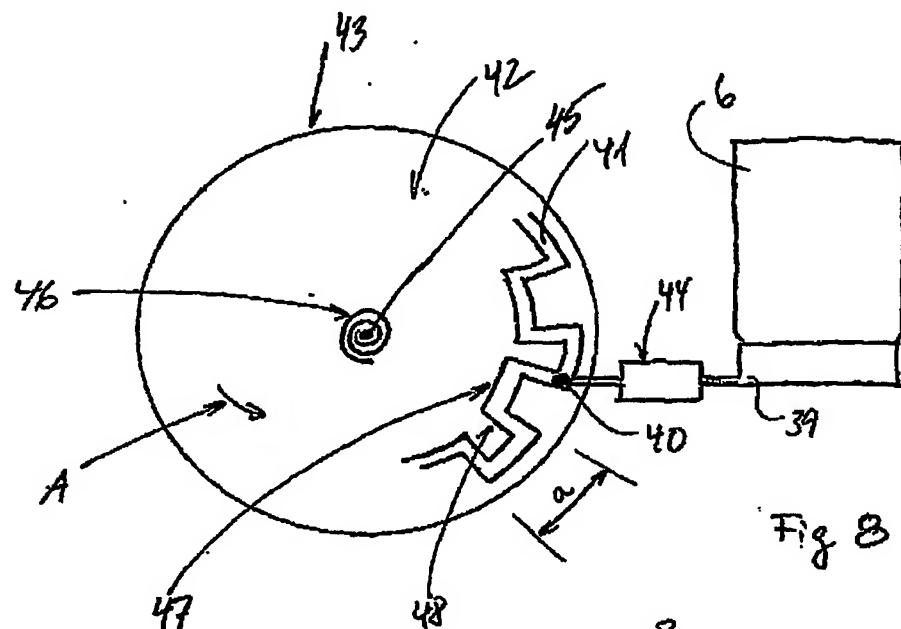
PVS





Modtaget  
04 NOV. 2002

PVS



Modtaget

04 NOV. 2002

PVS

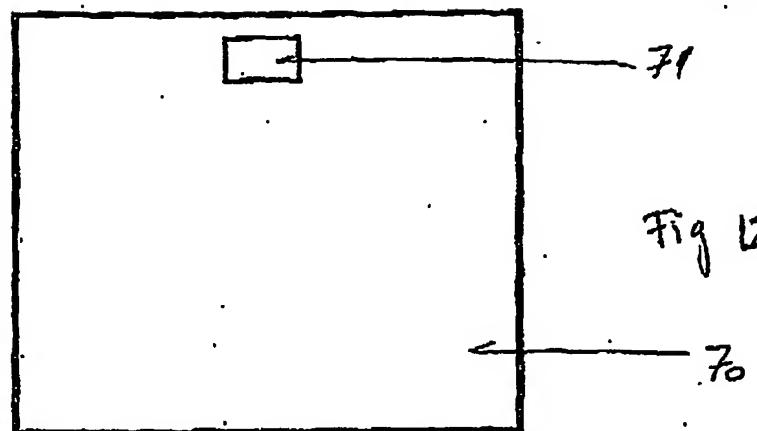


Fig 12

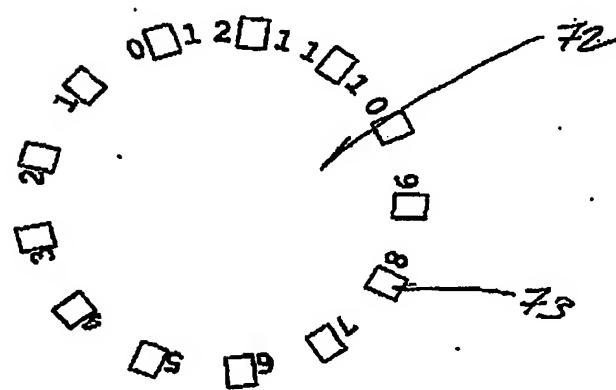


Fig 13

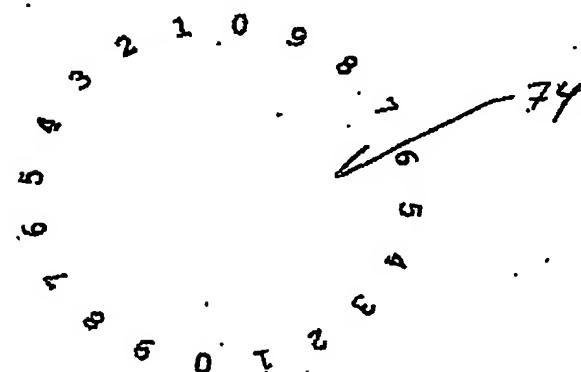


Fig 14

Modtaget

04 NOV. 2002

PVS

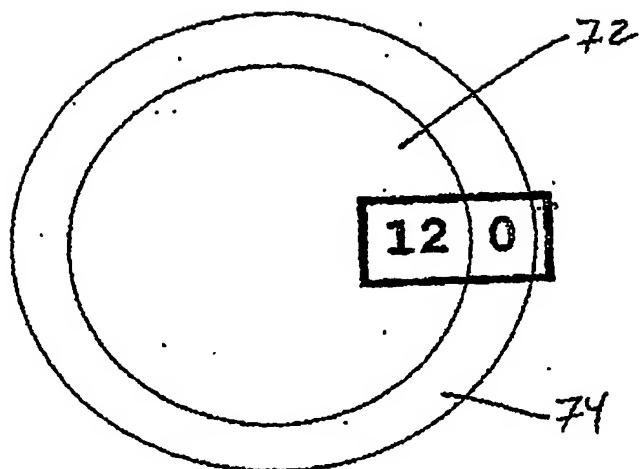
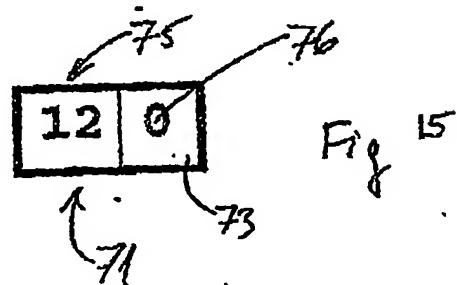


Fig 16



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**